## BEST AVAILABLE COPY

540.91195 CP2

## What is claimed is:

1. A method of preparing a bioavailable sustained release oral dosage form comprising combining a sustained release excipient with a medicament in amorphous form and a wetting agent and then drying and milling the resulting combined composition and

said sustained release excipient comprises a gelling agent, an ionizable gel enhancing agent and an inert diluent, the ratio of inert diluent to gelling agent being from about 1:8 to about 8:1, said ionizable gel strength enhancing agent increasing the gel strength of a gel formed when said solid dosage form is exposed to environmental fluid, and said gelling agent comprises xanthan gum and locust bean gum and said locust bean gum being from about 1:3 to about 3:1; wherein the amorphous form of said medicament affects the bioavailability of said oral dosage form.

- 2. The method of claim 1, wherein the medicament has an aqueous solubility of less than 10 g/liter.
  - 3. The method of claim 1, wherein the wetting agent is polyethylene glycol.
- 4. The method of claim 1, wherein said medicament is selected from the group consisting of nifedipine, nimodipine, nivadipine, nitrendipine, nisolidipine, niludipine, nicardipine and felodipine.
  - 5. The method of claim 4 wherein said medicament is nifedipine.
- 6. The method of claim 3 wherein the polyethylene glycol is mixed with water to form a polyethylene glycol-water slurry prior to the combination of the medicament with the excipient.
- 7. The method of claim 1, wherein said medicament, gelling agent, ionizable gel strength enhancing agent and inert diluent are combined by dry blending.

## **BEST AVAILABLE COPY**

540.91195 CP2

- 8. The method of claim 7, wherein said wetting agent admixed with the dry blended mixture of medicament, gelling agent, ionizable gel enhancing agent and inert diluent and drying and milling the resultant mixture.
- 9. The method of claim 7, wherein said mixture of medicament, gelling agent, ionizable gel enhancing agent and inert diluent are premanufactured as a sustained release excipient.
- 10. The method of claim 8, wherein cellulose is added to the wetting agent before the addition of the medicament, gelling agent, ionizable gel enhancing agent and inert diluent.
- 11. The method of claim 10 further comprising dissolving the medicament in the wetting agent and then adding the gelling agent, ionizable gel enhancing agent, inert diluent and cellulose to the resulting combination.
- 12. The method of claim I wherein the gelling agent comprises at least one naturally occurring gum suitable for forming a sustained release gel upon contact with environmental fluid.
- 13. The method of claim 1 wherein said gelling agent further comprises an agent selected from the group consisting of alginates, carrageenan, pectin, guar gum, xanthan gum, locust bean gum, modified starch, cellulose and mixtures of any of the foregoing.
- 14. The method of claim 10 wherein said cellulose is selected from the group consisting of hydroxypropylmethylcellulose, methylcellulose, sodium carboxymethylcellulose and hydroxypropyl cellulose and mixtures of any of the foregoing
- 15. The method of claim 1 wherein said ionizable gel strength enhancing agent is selected from the group consisting of monovalent, divalent and multivalent organic or inorganic salts and mixture thereof.

## BEST AVAILABLE COPY

540.91195 CP2

- 16. The method of claim 1 wherein said ionizable gel strength enhancing agent comprises an alkali metal or an alkaline earth metal sulfate, chloride, borate, bromide, citrate, acetate or lactate.
- 17. The method of claim 1, wherein said composition further comprises an amount of a pharmaceutically acceptable hydrophobic material effective to slow the hydration of the gelling agent when said solid dosage form is exposed to gastrointestinal fluid.
- 18.. A method of treating a patient comprising administering a dosage form prepared according to claim 1 to a patient in need of antihypertensive treatment.